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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,515	11/06/2003	Said I. Hakky	MR2493-38	7376

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ELLICOTT CITY, MD 21043

EXAMINER

BOGART, MICHAEL G

ART UNIT PAPER NUMBER

3761

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/701,515	Applicant(s) HAKKY ET AL.	
	Examiner Michael G. Bogart	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>26 Mar. 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there is no antecedent basis for claim 7's recitation of the wire being made of metallic or non-metallic material with a predetermined stiffness.

Claim Objections

Claims 1, and 7-9 are objected to because of the following informalities:

In the last line of each of claims 1, 8 and 9, respectively, "sytle" appears to be a typographical error.

Appropriate correction is required.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

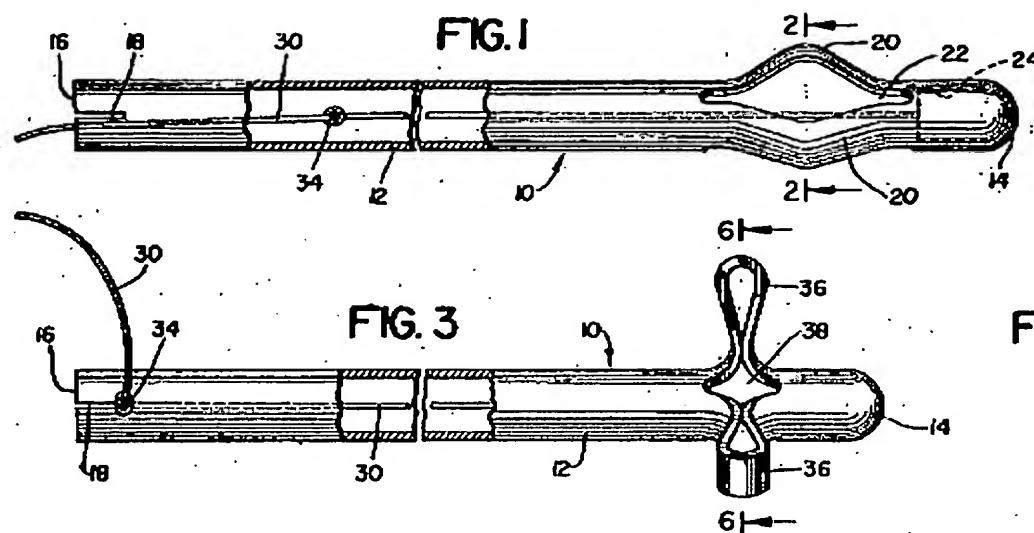
Claims 1-3, 7, 8 and 12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Wallace (US 2,649,092).

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Regarding claim 1, Wallace teaches a self-retaining urinary drainage catheter system (10), comprising:

(a) a longitudinally extending flexible tube (12) having a predetermined outer diameter, an open distal end (16) and a closed proximal end (14), said flexible tube (12) defining at least one lumen, said closed proximal end (14) having a plurality of longitudinally directed slits (22) formed through a wall of said flexible tube (12) defining a plurality of flexible tube (12) slit portions (20, 36); and,

(b) means (30) for reversibly and radially displacing said plurality of flexible tube slit portions (20, 36) of said proximal end (14) to a first configuration (fig. 1) abutting in a non-continuous manner an inner surface of a urinary bladder, said first configuration of flexible tube slit portions (20, 36) having an outer diameter greater than said predetermined diameter of said flexible tube (12) and defining a plurality of drainage apertures (38), and for displacing said plurality of flexible tube slit portions (20, 36) to a second configuration (fig. 2) wherein said plurality of flexible tube slit portions (20, 36) has a diameter substantially equal to said predetermined outer diameter of said flexible tube (12), wherein said means (30) do not substantially obstruct a lumen of said catheter (10), and said catheter (10) is reversably insertable in a human being without using a stylet (see figures 1 and 2, below).



Regarding claims 2 and 8, Wallace teaches that said means (30) further comprises a wire control device (30) longitudinally and slidably positioned within a lumen of said longitudinally extending flexible tube (12), said wire control device (30) fixedly secured at a first end (32) to an inner surface of said closed proximal end (14) and having a length greater than a length of said longitudinally extending flexible tube (12) so that a second end of said wire control device (30) protrudes through said open distal end (16)(figure 1).

Regarding claims 3 and 12, Wallace teaches that said wire control (30) device further comprises a means (18, 34) for reversibly locking said wire control device (30) in a predetermined position (figure 3).

Regarding claim 7, Wallace teaches that the wire control device (30) is composed of a metal or non-metallic material (polyethylene)(column 3, lines 11-18).

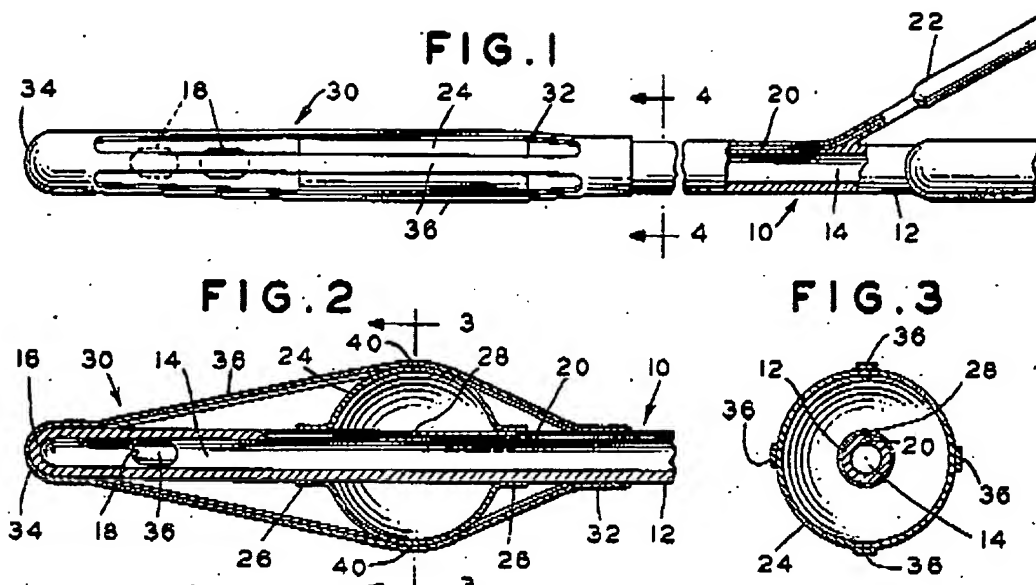
Claims 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Baskin (US 2,854,983.

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Regarding claim 1, Baskin teaches a self-retaining urinary drainage catheter system (10), comprising:

(a) a longitudinally extending flexible tube (12) having a predetermined outer diameter, an open distal end and a closed proximal end (34), said flexible tube (12) defining at least one lumen (14), said closed proximal end (34) having a plurality of longitudinally directed slits (32) formed through an outer wall of said flexible tube (12) defining a plurality of flexible tube slit portions (32); and,

(b) means (20, 24) for reversibly and radially displacing said plurality of flexible tube slit portions (32) of said proximal end (34) to a first configuration (fig. 2) abutting in a non-continuous manner an inner surface of a urinary bladder, said first configuration of flexible tube slit portions (32) having an outer diameter greater than said predetermined diameter of said flexible tube (12) and defining a plurality of drainage apertures, and for displacing said plurality of flexible tube slit portions (32) to a second configuration (fig. 1) wherein said plurality of flexible tube slit portions (32) has a diameter substantially equal to said predetermined outer diameter of said flexible tube (12), wherein said means (20, 24) do not substantially obstruct a lumen (14) of said catheter (10), and said catheter (10) is reversibly insertable in a human being without using a stylet (see figures 1 and 2, below).



Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

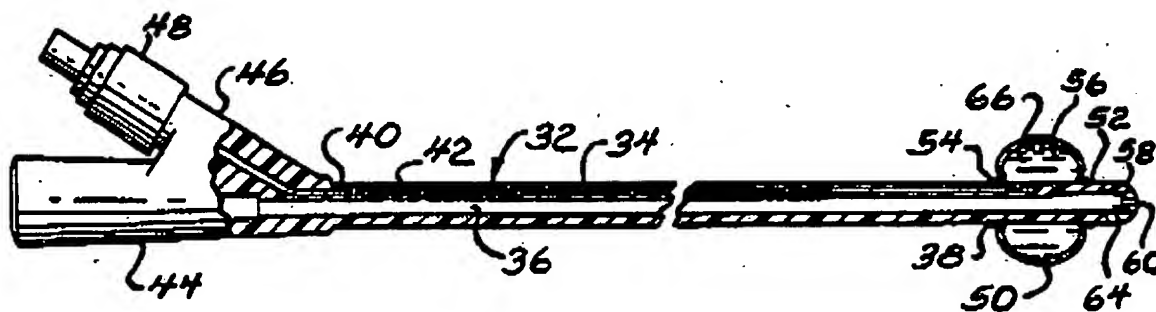
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Claims 4-6 and 9-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Baskin as applied to claim 1 above, and further in view of Rosenberg (US 4,787,892).

Regarding claims 4 and 9, Baskin teaches that said means (20, 24) for reversibly and radially displacing said plurality of flexible tube slit portions (32) further comprises a reversibly inflatable balloon (24) located between said plurality of flexible tube slit portions (32) and having flexible non-distensible tubing allowing fluid to be reversibly injected therein so as to expand said reversibly inflatable balloon (24).

Baskin does not expressly disclose a valve.

Rosenberg teaches a balloon catheter (32) having a balloon inflation tube (42) that controls fluid flow to the balloon via a valve (48)(figure 6).



At the time of the invention, it would have been obvious to one of ordinary skill in the art to add the valve of Rosenberg to the fluid inflation tube of the catheter of Baskin in order to provide a means of keeping the balloon inflated.

Regarding claims 5 and 10, Baskin teaches a spherical balloon (24)(figure 2).

Regarding claims 6 and 11, Rosenberg teaches an oblong balloon (50)(figure 6).


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Bogart
1 December 2005

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

